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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/202,984 09/19/99 CZERNILOFSKY

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EXAMINER

CHAKRABARTI, A

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 06/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/202,984

Applicant(s)
Czernilofsky

Examiner
Arun Chakrabarti

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 20, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 273.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 23-26 is/are rejected.
- 7) ☒ Claim(s) 5-22 and 27 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/202,984.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-882) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 20) ☐ Other:

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DETAILED ACTION

Specification

1. Claims 5-22 and 27 are objected to under 37 CAR 1.75© as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as indefinite because the instantly claimed method lacks a final process step that clearly relates back to the preamble. For the method of claim 1, the preamble of the instantly claimed method is drawn to a process for determining the pharmacological effect of a substance on the activity of various biological target molecules while the final process step is that of using different detection methods directly compared with one another in step b (ii) and it is thus unclear as to whether the instantly claimed methods are drawn to a process for

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determining the pharmacological effect of a substance on the activity of various biological target molecules or rather using different detection methods directly compared with one another.

Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claim 1 lacks such a last step and are confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See *Ex parte Erlich*, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim 1 is rejected over the recitation of the phrase, "basic biological constitution". It is not clear what kind of constitution is claimed. Are the nucleus, mitochondria, plasma membrane, golgi apparatus and other subcellular compositions claimed or the functional characteristics of particular cells claimed or nucleic acids, proteins and lipids characteristic of a particular kind of cells claimed? The metes and bounds of the claim is vague and indefinite.

Claim 1 is rejected over the recitation of the phrase, "one operation". It is not clear what kind of operation is claimed. Is the whole method carried out in one vessel or in one step or by one person or by a particularly special and innovative methodology. The metes and bounds of the claim is vague and indefinite.

Claim 23 is rejected over the recitation of the phrase, "in question". It is not clear what is the question, who is making the question, what is the answer and who is answering the question. The metes and bounds of the claim is vague and indefinite.

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 23-24 and 26 are rejected under 35 U.S.C. 102 (b) as being anticipated by Foulkes et al. (PCT international Publication number WO 92/13063) (August 6, 1992).

Foulkes et al teach a process for determining the pharmacological effect of a substance on the activity of various biological target molecules, wherein a substance is applied to test cells which contain one or more biological target molecules and the effect of the substance on the activity of the target molecules is determined, characterized in that in one operation a defined amount of a test substance (Claims 67-72 and 104 and Page 56, line 5 to page 61, line 20)

a) is applied to test cells with the same basic biological constitution which differ in that they contain one or more different biological target molecules (Claims 67-72 and Claims 92-102 and page 56, Addition of chemicals to cells Subsection); and/or

b) is applied to test cells which contain one or more biological target molecules, the cells differing in that they have different basic biological constitutions (Claims 67-72 and Claims 92-102 and page 56, Addition of chemicals to cells Subsection); and

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I) the effect of the substance on the or each biological target molecule is measured using a detection system coupled to the activation of the target molecule (Claims 94-103 and Page 57, line 5 to page 58, line 8); and/or

ii) the effect of the substance on different regulatory mechanisms triggered by the activation of the target molecule is determined by measuring the effects using a plurality of detection systems each coupled to the different regulatory mechanisms, and the effects of the test substance on the different test cells or the effects determined using different detection methods are directly compared with one another (Figure 20 and Page 58, line 13 to page 59, line 12).

Foulkes et al teach a process characterized in that a plurality of substances, optionally in several dilutions, are applied in parallel to one or more sets of cellular substrates, each set constituting a group of different assays or assay formats based on the same targeting cell (Claims 84-87 and page 56, Addition of chemicals to cells Subsection).

Foulkes et al teach a process characterized in that the test cells are mammalian and human cells (Claims 76-79 and Page 42, line 5 to page 43, line 11).

Foulkes et al teach a process characterized in that the test cells contain a reporter gene under the control of a regulatory sequence which responds to the change in the concentration of a messenger substance of a signal transmission pathway, of which the target molecule is a component, and that the effect of the test substance on the target molecule is determined in a change in the expression of the reporter gene (Figures 1-4, 6-9 and 11-12 and Page 57, line 5 to page 58, line 8 and Figures 20-24);

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Foulkes et al teach a process characterized in that the reporter gene is luciferase (Figures 1-4, 6-9 and 11-12 and Page 57, line 5 to page 58, line 8).

Foulkes et al teach a process characterized in that the test cells which are dependent on a growth factor for their proliferation are cultivated in the presence of the growth factor and the effect of the substance on the cells is determined by indirectly measuring the apoptosis or the proliferation of the cells (Page 2, line 23 to page 5, line 5 and Page 42, line 5 to page 43, line 11 and Figure 20).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 1-4 and 23-26 are rejected under 35 U.S.C. 103 (a) over Foulkes et al. (PCT international Publication number WO 92/13063) (August 6, 1992) in view of Chapman et al. (U.S. Patent 6,232,099 B1) (May 15, 2001).

Foulkes et al teach the process of claims 1-4, 23-24 and 26 as described above.

Foulkes et al do not teach the Green fluorescent protein as the reporter gene.

Chapman et al teach the Green fluorescent protein as the reporter gene (Examples 1 and 2 and Figures 1a and 1b).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the Green fluorescent protein of Chapman et al. in the process of Foulkes et al., since Chapman et al. state, "The green fluorescent protein (GFP) from *A. Victoria* is a reporter of gene expression in heterologous systems. GFP has an advantage over other marker proteins in that it can be detected non-invasively, without any requirement for exogenous substrates or co-factors since it fluoresces intrinsically without a requirement for exogenous substrate. In addition, fluorescence of GFP is retained in fusion proteins allowing the subcellular localization of fusion proteins (Column 7, line 66 to column 8, line 7)." An ordinary practitioner would have been motivated to combine and substitute the Green fluorescent protein of Chapman et al. in the process of Foulkes et al. in order to improve the process for determining the pharmacological effect of a substance on a cell and also in order to achieve the express advantages, as noted by Chapman et al., of a protein which has an advantage over other marker proteins in that it can be detected non-invasively, without any

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requirement for exogenous substrates or co-factors since it fluoresces intrinsically without a requirement for exogenous substrate and in addition, fluorescence of which is retained in fusion proteins allowing the subcellular localization of fusion proteins.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Arun Chakrabarti,

Patent Examiner,

June 7, 2001


JEFFREY FREDMAN
PRIMARY EXAMINER